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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,027	08/28/2003	Laurent Schaller	CSI-2008C2	1555

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Jeffrey J. Hohenshell
710 Medtronic Parkway
Minneapolis, MN 55432

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3773

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02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/653,027	Applicant(s) SCHALLER ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/11/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 8-35 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 26 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, 8-11, 18, 28, 29 and 31-35 is/are rejected.
- 7) ☒ Claim(s) 12-17, 19-23, 25, 27 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on December 11, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Application No. 10/208,405 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Seitzinger (5,374,268). Seitzinger discloses, at least in the figures and col. 2, lines 28-65; a tissue connector assembly, where the assembly includes first and second tissue piercing members (16, 18), a surgical fastener (10) adapted to assume a loop configuration (See fig. 2, where it has assumed a loop configuration within element 20; or fig. 3, where it has begun to assume a loop configuration from pulling of the piercing members) and having first and second end portions, the first tissue piercing member being coupled to the first end portion and the second tissue piercing member being coupled to the second end portion (via 12 and 14, respectively); a flexible

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member (12) with a first end portion coupled to the first tissue piercing member and a second portion having coupled to the first end portion of the fastener, a second flexible member (14) having a first end portion coupled to the second tissue piercing member and a second end portion coupled to the second end portion of the fastener, where the flexible members comprise a suture, and where the tissue piercing members comprise needles.

4. Claims 1, 28, 29, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pyka et al. (5,002,563). Pyka et al. disclose, at least in figures 2-5B2 and col. 4, lines 26-58 and col. 6, lines 7-56; a tissue connector assembly (10) including a surgical fastener (18 or 12) adapted to assume a loop configuration, a first tissue piercing member (14), a second tissue piercing member (32 with a "sharpened distal end"), and a flexible member comprising a suture (16), where the surgical fastener has first and second end portions, the first tissue piercing member being coupled to the first end portion (via 16) and the second tissue piercing member being coupled to the second end portion (via 18), where the flexible member (16) has a first end portion coupled to the first tissue piercing member and a second end portion coupled to the first end portion of the fastener (12 as seen in fig. 1, or 18 as seen in fig. 4A), where surgical fastener comprises a clip or wire of shape memory material, and where the clip has an open (as seen in fig. 30 and a closed (as seen, e.g., in fig. 2 or 5B1) configuration.

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5. Claims 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolduc et al. (6,254,615). Bolduc et al. disclose, at least in figures 12F and 12G and in col. 16, line 62 to col. 17, line 14; a tissue connector assembly including a surgical fastener (222) adapted to assume a loop configuration and having first and second end portions, a first discrete tissue piercing member (point of 220a) coupled to the first end portion and a second tissue or discrete tissue piercing member (point of 220b) coupled to the second end portion, where the surgical fastener comprises a clip having an open configuration (see fig. 12F) and a closed configuration (see fig. 12G), where the clip is in the closed configuration when in a relaxed state, and where the clip is generally U-shaped in the open configuration and assumes a spiral configuration in the closed configuration.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seitzinger (5,374,268) in view of Kaufman et al. (3,125,095). Seitzinger discloses the invention substantially as claimed, but does not disclose that the flexible member comprises metal. Kaufman et al. teach, at least in figure 1 and col. 1, lines 19-25; a flexible member comprising metal (stainless steel). It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply a metallic flexible member as taught by Kaufman et al. in the device of Seitzinger. Such a flexible member would possess great strength and flexibility for retracting a body organ with little risk of breakage.

8. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seitzinger (5,374,268) in view of Totakura et al. (5,383,904). Seitzinger discloses the invention substantially as claimed, but does not disclose first and second couplings where the first tissue piercing member and the first end portion of the fastener are coupled to the first coupling, and the surgical fastener second end portion and second piercing member are coupled to the second coupling. Totakura et al. teach, at least in the figure and col. 1, lines 31-48 and col. 1, line 61 to col. 2, line 30; couplings (22, when covering 100% of flexible members 12a and 12b) respectively coupling first and second piercing members (16a, 16b) to first and second end portions of a surgical fastener (14). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Totakura et al., to include couplings with the tissue connector assembly of Seitzinger. Such couplings would allow stiffening of

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flexible members and substantially eliminate the tendency of the flexible members to become tangled or twisted about the surgical fastener.

Allowable Subject Matter

9. Claims 24 and 26 are allowed.

10. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a tissue connector assembly including, inter alia, a surgical fastener adapted to assume a loop configuration, first and second tissue piercing members, a coupling and a second coupling, a flexible member, and a coil, where the coil surrounds the surgical fastener and is compressed against the second coupling, and where the second coupling includes a first member fixedly secured to the fastener and a second member slidably coupled to the fastener. Also, none of the prior art of record, alone or in combination, discloses a tissue connector assembly including, inter alia, a surgical fastener adapted to assume a loop configuration, first and second tissue piercing members, a coupling and a second coupling, and a flexible member, where the flexible member has a portion coupled to the second tissue piercing member and a knotted portion, the second coupling including a tubular member having a bore, and the knotted portion being in the bore.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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11. Claims 12-17, 19-23, 25, 27, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a tissue connector assembly including, inter alia, a surgical fastener adapted to assume a loop configuration, first and second tissue piercing members, a coupling and a second coupling, and a flexible member comprising a suture, where the coupling comprises a tubular member having movable portions and the surgical fastener includes an enlarged portion adapted for receipt in the movable portions, where the second coupling releases the second piercing member and the surgical fastener in response to releasing the fastener first end portion coupling, where a coil surrounds the surgical fastener or surgical clip wire, where the fastener includes a groove and projection and the second coupling includes a member having a groove, projection and sleeve; and where the second coupling includes an annular blade.

Response to Amendment

13. Applicant's arguments with respect to claims 1, 3, 5, 6, 8-11, 18, 28, 29, 31, and 32 have been considered but are moot in view of the new ground(s) of rejection.

The arguments regarding the rejection of claims 33-35 based on the Bolduc reference have been considered but are not persuasive. That is, the Examiner agrees with the Applicant that Bolduc discloses a "single fastener." However, the fastener

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comprises members and portions as claimed. The ENCARTA World English Dictionary defines "member" to include an "individual part: a separate and distinct part of a whole." The tissue piercing members (220a, 220b) are described by Bolduc as "needle portions," which are separate and distinct parts of the whole fastener. The fastener also includes a surgical clip (222) with portions coupled or joined to the needle portions. The clip, which includes "loop 224," indeed has a "spiral configuration." The ENCARTA World English Dictionary defines "spiral" to include "continuously curving with flat curves or series of curves that constantly increase or decrease in size in circling around a central point." The spiral of Bolduc's clip meets this description. Also, the spiral of Bolduc's clip can also assume a closed configuration (as seen in fig. 12G and as compared to the open configuration in fig. 12F). The mention of a relaxed state "in a patient's body" in the Office action of July 11, 2008 was a reference to the fact that a closed configuration of the clip can occur in a patient's body, if the clip were to be made of a shape memory material that is responsive to body temperature (See Bolduc, col. 17, lines 2-8).

The double patenting rejection in the Office action of July 11, 2008 is hereby withdrawn in view of the approved terminal disclaimer that was filed December 11, 2008.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773